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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/055,744 | 04/07/1998 | CHARLES D. Y. SIA | 1038-746-MIS | 4350 |

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| EXAMINER | |
|---|---|
| LE, EMILY M | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1648 | |

DATE MAILED: 05/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/055,744 | SIA ET AL. | |
| | Examiner | Art Unit | |
| | Emily Le | 1648 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspond nc address --*

**Peri d for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *3/15/02, 5/13/02, 1/17/03*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disp sition of Claims**

4)☒ Claim(s) *1 and 4-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 4-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 April 1998* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: Notice to Comply

## DETAILED ACTION

### *Art Unit Location*

1. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1648, Examiner Emily Le.

### *Request For Continued Examination*

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/18/02, 5/13/02, and 01/17/03 has been entered.

### Status of Claims

3. Claims 2-3 were cancelled. Claims 1 and 4-15 are currently pending and under examination.

### *Sequence Listing*

4. Applicant's "Voluntary Amendment" fails to place the instant application into sequence compliance for the following reasons:

5. The sequence pages contain new matter. The contents disclosed thereon do not match those that are presented in the original specification. For example, page 3 of the sequence pages that is submitted as Paper No. 4, on June 14, 1999, indicates that SEQ ID NO: 9 contains 65 amino acids. However, the sequence, "RQIHSISERILSTYLGRSAEPVPLQLPPLERLTLDCNEDCGTSGTQGVGSPQILVESPA

VLESGTKE", that is presented in the specification (Table 2, page 17), by original presentation, indicates that SEQ ID NO: 9 contains 67 amino acids,

***Drawings***

6. New corrected drawings are required in this application because the submitted drawings contain text that is not clearly written, for example, see Figure 2. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

7. The drawings are objected to because the data that is presented in the drawings are incomprehensible because the graphs presented in the drawings lacks notation of both the X and/or Y-axes, i.e., see Figure 1. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance. Applicant is advised against the addition of new matters to the drawings or specification.

***Specification***

8. The disclosure is objected to because of the following informalities: lines 19-22 of page 7 disclose a set of sequences that are capable of binding to HLA-A2 molecules. However, this set of sequences is not the same as those disclosed in lines 12-14 of page 5 in the specification. It is acknowledged that the designation "CLP-#" is the same. It is the "SEQ ID NO:" designation that is incorrect.

Appropriate correction is required.

### *Claim Objections*

9. Claims 1 and 10 are objected to because of the following informalities: The preamble of the claims directs the claimed invention to a "method of generating an HIV-specific cytotoxic T-cell (CTL) response", yet the conclusionary aspect of the claims recite "to generate an HIV-specific T-cell response". Applicant is hereby requested to amend the claims so the preamble of claimed method and the conclusionary part of the same method are directed to the same population, either an HIV-specific cytotoxic T-cell (CTL) response OR an HIV-specific T-cell (CTL) response. In addition, the acronym is recognized in the art as cytotoxic T-lymphocyte not cytotoxic T-cell.

This also affects claims 2-9 and 11. Appropriate correction is required.

### *Claim Rejections - 35 USC § 101*

10. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

11. Claims 12-15 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are directed to peptides consisting of a multitude of sequences. Currently, as written, the claims read on a product of nature. The claims do not require the claimed peptide be isolated peptide, which implies that the "hand-of-man" was involved. Therefore, because the claims read on a product of nature, the claims are directed to non-statutory subject matter under 35 U.S.C. 101.

### *Claim Rejections - 35 USC § 112*

12. Claims 1 and 4-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Currently, as written, it is unclear what the metes and bounds are of the peptide that is recited in claims 12-15. The claims recited a peptide consisting of SEQ ID NO: 9; however, the claims also require that the peptide contain, "containing", different epitopes that is denoted as SEQ ID NO: 3, 5, and 8. So, currently as written, it is unclear if the cited epitopes are to reside i) within the peptide that is defined by SEQ ID NO: 9, ii) outside the peptide that is defined by SEQ ID NO: 9, or iii) a mixture of within and outside the peptide defined by SEQ ID NO: 9. If the peptide contains a mixture of the cited epitopes within and outside of the peptide defined by SEQ ID NO: 9, then which epitopes are within SEQ ID NO: 9 and which are outside of SEQ ID NO: 9. In addition, if what is intended by such recitation is that the cited epitopes are to reside within the peptide that is defined by SEQ ID NO: 9, a discrepancy is noted between what is instantly claimed and what is recited in the specification. As mentioned above, the claims are directed to SEQ ID NO: 9 and if the claims are interpreted to require the listed epitopes, SEQ ID NO: 3, 5, and 8, to be within SEQ ID NO: 9. However, the specification teaches that SEQ ID NO: 9 comprises the following epitopes: SEQ ID NO: 3, 4 and 8, within in SEQ ID NO: 9. The set of epitopes that is provided in the specification is not that instantly claimed.

Furthermore, concerning claims 1 and 4-11, the claims contain the limitation "a T-cell inducing HIV molecule" is vague and indefinite. The precise physical and immunological properties of this compound are not readily manifested. Does the molecule induce a humoral, cell-mediated, T-helper cell, or some other response? Secondly, the precise chemical nature of this compound is not readily manifested.

Does the compound reference a peptide carrying a particular epitope, an adjuvant, or some other molecule?

In addition, currently as written, it is unclear what is intended by the following recitation "and which is a lipopeptide" in line 7 of claim 10. Is the recitation directed to the T-cell inducing HIV molecule or the T-helper molecule? Moreover, it is unclear which of the above molecules, T-cell inducing HIV molecule or the T-helper molecule, is denoted as CLP-175 or CLP-176.

Claims 9 and 14 recite the limitation "the lipid" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim.

In view of the discussion above, the claims are rendered indefinite.

13. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. Claims 1 and 4-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a **NEW matter** rejection.

Support cannot be found within the specification for the following recitation " a host possessing MHC class I HLA A2 molecules".

15. Claims 1, 5-9 and 11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to a genus of T-helper molecules. However, the specification only teaches SEQ ID NO: 10 as the T-helper molecule. The T-helper molecule, SEQ ID NO: 10, that is taught in the specification does not adequately describe or sufficiently represent the genus of T-helper molecules that are instantly recited in the claims. Furthermore, Applicant has not provided the specific activities that T-helper molecules must possess to allow one skilled in the art to recognize the T-helper molecules that are referred to in this instantly claimed invention.

16. Claims 1, 4-9 and 11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to a genus of T-cell inducing molecules capable of binding to HLA-A2 molecules. However, the specification only teaches that SEQ ID NO: 2, 8, 3 and 7 as T-cell inducing molecules that are capable of binding to HLA-A2 molecules (lines 12-14 of page 5 of the specification). The number of T-helper molecules that are taught in the specification does not adequately nor does it sufficiently represent the genus of T-cell inducing molecules that are instantly recited in the claims. Furthermore, Applicant has not provided the specific activities that T-cell inducing molecules must possess to allow one skilled in the art to recognize T-cell inducing molecules that are referred to in this instantly claimed invention. It is acknowledged

that the claims require that the T-cell inducing molecules to be capable of binding to MHC class I HLA A2 molecules. However, currently as written, the claims do not require that T-cell inducing molecules to possess a particular activity because the term capable is a conditional term. T-cell inducing molecules that are capable of binding to MHC class I HLA A2 molecules does not necessarily mean that the T-cell inducing molecules binds to MHC class I HLA A2 molecules.

17. Claims 1 and 4-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. In Genentech *Inc. v. Novo Nordisk* 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997); *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); See also *Amgen Inc. v. Chugai Pharm. Co.,* 927 F.2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed. Cir. 1991); *In re Fisher* 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Further, in *In re Wands* 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) the court stated:

> Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman* [230 USPQ 546, 547 (Bd Pat App Int 1986)]. They include (1) the quantity of

experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The instantly claimed invention is directed a method of generating an HIV-specific cytotoxic T-cell (CLT) response in a host comprising a prime and boost protocol. The priming protocol requires the administration to a host a T-helper molecule to prime T-helper cells of the immune system of the host. The boost protocol requires the administration to the host a mixture of T- helper molecule and a T-cell inducing HIV molecule that is capable of binding to MHC class I HLA A2 molecules. The overall purpose of such prime and boost protocol is to generate an HIV-specific T-cell response in the host. Therefore, the nature of the invention is directed to a method that comprises a prime and boost protocol that uses T-helper molecules and T-cell inducing HIV molecules to generate an HIV-specific cytotoxic T-cell (CTL) response in a host. While it is acknowledged, from Applicant's 10//12/2001 response, that Applicant does "not promise that the procedure of the invention is a vaccination procedure against HIV and neither does Applicants [Applicant's] data demonstrated the same"; however, this does not evade the obvious fact that the instantly claimed invention reads on a vaccine method that is used to treat and/or prevent HIV infection through the generation of HIV-specific cytotoxic T-cell response in a host. The nexus between the instantly claimed invention, in it's fullest scope, to the treatment and prevention of HIV infection is arrived at based on the disclosure that is provided by Applicant in the specification. For

example, on page 2 of the specification, Applicant admits that peptides containing "the Rev protein..., may be presented in the context of the Major Histocompatibility Complex (MHC) class 1 molecules to induce CTL effector response capable of killing virus infected cells early to limit virus spread."

The instantly claimed invention comprises the administration of peptides that are derived from the Rev protein. These peptides are presented in the context of the Major Histocompatibility Complex (MHC) class I molecules because the claims require that the T-cell inducing HIV molecule is capable of binding to MHC class I molecules. Furthermore, the preamble of the method requires that the practice of the claimed invention generates or induce a HIV-specific CTL response. Therefore, in view of what is currently presented in the claims, in light of the disclosure provided in the specification, it is concluded that the full breadth of the claimed invention encompasses an in vivo vaccine method that is used to treat, prevent, or inhibit the progression of HIV infection in humans and non-human animals by generating an HIV-specific CTL response in the host.

The amount of guidance that is provided in the specification that is directed to the instantly claimed invention, any scope of the claimed invention, is very limited.

The nature of the claimed invention is directed to an in-vivo vaccine method. However, the specification does not contain any in vivo working examples, with the exception of Example 3, in which a the prime and boost protocol was used. However, the findings or results observed from the study cannot be used as a teaching of the instant invention because the information rendered is not directed to the measurement of HIV-specific CTL response in a host. The measurement made from the study was

anti-CLP-164 antibody response, wherein the in data is presented in Figure 2. The information presented in Figure 2, which is derived from Example 3, does not enable one skilled in the art to practice the claimed invention without an undue burden because the example does not demonstrate the following: i) the administration of T-helper molecule primes the immune system of the host; ii) anti-T-cell inducing HIV molecule (denoted as anti-CLP-164) IgG titre **increases** when the mice are primed with a T-helper molecule (CLP-243, also denoted as SEQ ID NO: 10), and boosted with a mixture of T-helper molecule and T-cell inducing HIV molecule. This is so because the data presented in each graphs indicate that anti-T-cell inducing HIV molecule IgG titre both **increases and decreases** when the mice are primed with a T-helper molecule and boosted with a mixture of T-helper molecule and T-cell inducing HIV molecule from one mouse to another mouse. The data presented lacks consistency with one another; and iii) above all, the response induced, if any, is an **HIV-specific** cytotoxic T-cell response. Therefore, this working example does not support the instantly claimed invention.

The other working examples that are provided in the specification are all in vitro. Although in vivo working examples are not required for a claimed in vivo method, however, Applicant is required to show that the findings from in vitro experiments correlate with an in vivo use of the claimed method. Without such correlation, it is unclear if the practice of the instantly claimed prime and boost protocol of the instantly claimed method would lead to the generation of an HIV-specific cytotoxic T-cell (CTL) response. Even if a in vitro and in vivo correlation is provided, the working examples of the instant specification does not enable one skilled in the art to practice the claimed invention without an undue burden because the specification does not contain any

working examples that demonstrate that the implementation of the claimed method leads to the generation of HIV-specific cytotoxic T-cell (CTL) in a host. Additionally, the working examples provided in the instant specification do not commensurate with any scope of the claimed invention. Moreover, because the claims require i) priming of the immune system of the host, and ii) the generation of an HIV-specific T cell response in the host, it appears that only an in vivo study would be adequate.

Furthermore, it is well known in the art that retroviral infections in general, and HIV infections in particular, are refractory to anti-viral therapies. The obstacles to HIV/AIDS therapy and vaccine formulations are well documented in the literature. The obstacles includes:

i) the inability current vaccine designs to elicit effective neutralizing antibodies against circulation strains of HIV[1, 2],

ii) the inability of current vaccine designs to prevent HIV from establishing persistent infection [3],

iii) the extensive global variability of HIV[4, 5, 6, 7, 8],

iv) the lack of understanding regarding the mechanisms of protection[9,10],

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[1] Klausner et al. The need for a global HIV vaccine enterprise. Science, Vol. 300, June 2003, pp. 2036-2039, see underlined text.
[2] Desrosiers, Prospects for an AIDS vaccine. Nature Medicine, Vol. 10(3), March 2004, pp. 221-223, see underlined text.
[3] Ibid.
[4] Ibid.
[5] Nabel. Challenges and opportunities of development of an AIDS vaccine. Nature, Vol. 410, April 2001, pp. 1002-1007, see underlined text and Table 1.
[6] Desrosiers, opt. cit.
[7] Lee. Chapter 32 AIDS Vaccines: 32.1 Acquired immunodeficiency disease vaccines: design and development. AIDS: Biology, Diagnosis, Treatment, and Prevention, fourth edition, edited by DeVita, Jr. et al., Lippincott-Raven, 1997, pp. 605-616, see underlined text on page 609.
[8] Bende, et al. Update: Search for an AIDS vaccine. AIDS Read, 10(9), 2000, pp. 526-537, see Table 3.
[9] Klausner, op. cit.
[10] Desrosiers, op. cit

v) the lack of understating of which HIV antigens induce protective immunity and which immune effector mechanisms are responsible for protection[11],

vi) lack of immune correlates[12, 13, 14, 15],

vii) it is unknown if strong immune responses at muscosal surfaces will be necessary to provide protection from sexual transmission[16],

viii) inability to identify immunogens that induce broad and long lasting immunity[17], and

ix) lack of a practical animal model system for HIV. [18, 19,20,21, 22].

The existence of these obstacles establish that the contemporary knowledge in the art would not allow one skilled in the art to use the instantly claimed invention with a reasonable expectation of success and without undue experimentation.

Applicant has not provided any evidence that the instantly claimed method with the molecules that are instantly recited in the claims induces or generates HIV-specific CTL response. Moreover, Applicant has not provided any convincing evidence that the instantly method is indeed therapeutic against HIV infection by generating an HIV-specific cytotoxic T-cell (CTL).

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[11] Ibid.
[12] Nabel, op. cit.
[13] Beyrer, The HIV/AIDS vaccine research effort: An update. The Johns Hopkins University AIDS Service, The Hopkins HIV Report, Vol. 15 (1), January 2003, pp. 1-16, see pp. 6-7 and underlined text.
[14] Lee, op. cit., p. 608.
[15] Bende, op. cit.
[16] Ibid.
[17] Nable, op. cit.
[18] Feinberg et al. AIDS vaccine models: challenging challenge viruses. Nature Medicine, Vol 8 (3), March 2002, pp 207-210, see underlined text.
[19] Nabel, op. cit.
[20] Beyrer, op. cit.
[21] Lee, op. cit., p. 609.
[22] Bende, op. cit.

The specification does not teach or indicates that the immune response generated by the molecules is an HIV-specific cytotoxic T-cell response. And if an immune response observed is an HIV-specific cytotoxic T-cell response, there is no teaching in the specification whether the response generated would be sufficient to treat and/or prevent HIV infection. Nor does the specification teaches how much of such response would be necessary to treat HIV infection, prevent HIV infection, or even inhibit the progression of HIV infection by extending the latency of the virus. The specification also does not teach when the administration of such molecules, following the prime and boost protocol, should commence and end or the amount to administer to a host to accomplish the treatment and prevention of HIV infection, and inhibition of HIV progression.

Therefore, the disclosure in the specification does not contain sufficient guidance to allow one skilled in the art to practice the claimed invention with a reasonable expectation of success and without undue experimentation. In the absence of such guidance and evidence, the specification fails to provide an enabling disclosure. Therefore, in view of the above enablement analysis, one skilled in the art would not be able to practice the instantly claimed invention with a reasonable expectation of success without an undue burden of experimentation.

A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F. 2d 1557, 1562, 27 USPQ 2d 1510, 1513 (Fed. Cir. 1993).

***Double Patenting***

18. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 4-11 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 4-11 of copending Application No. 09/647,981 in view of the extent to which the claims are duplicates of one another. The claims of the instant invention are directed to a method of generating an HIV-specific cytotoxic T-cell (CTL) response in a host. The claims of the conflicting application are also directed to a method of generating an HIV-specific cytotoxic T-cell (CTL) response in a host. The difference between the two sets of

claims is the following: the claims of the instant application requires that that the "T-cell inducing HIV molecule capable of binding to MHC class I HLA A2 molecules" and that the '981 application does not. The '981 application only recites "a T-cell inducing HIV-derived molecule". However, such activities would be inherent characteristic of the T-cell inducing HIV molecules.

This is a provisional obviousness-type double patenting rejection.

***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

E.Le
Emily Le

Shanon Foley
Patent Examiner, AU 1648

| Notice to Comply | Application No. 09/055744 | Applicant(s) SIA et al. | |
|---|---|---|---|
| | Examiner Emily Le | Art Unit 1648 | |

## NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☐ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☒ 7. Other: The content of the submitted sequence listing, both paper and CRF, are not the same as those presented in the specification at the time of filing. See the attached office action for specific details.

### Applicant Must Provide:

☐ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

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